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PATENT COOPERATION TREATY

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NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE
in its capacity as elected Office

Date of mailing (day/month/year) 03 September 2001 (03.09.01)	
International application No. PCT/US00/24791	Applicant's or agent's file reference 23-00061-02
International filing date (day/month/year) 08 September 2000 (08.09.00)	Priority date (day/month/year) 08 September 1999 (08.09.99)
Applicant WILLIAMS, George, Roger	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
06 April 2001 (06.04.01)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer R. Forax Telephone No.: (41-22) 338.83.38
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PATENT COOPERATION TREATY

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REC'D 15 FEB 2002

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

WIPO

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(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 23-00061-02	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US00/24791	International filing date (day/month/year) 08 September 2000 (08.09.2000)	Priority date (day/month/year) 08 September 1999 (08.09.1999)
International Patent Classification (IPC) or national classification and IPC IPC(7): A63B 5/00 and US Cl.: 602/21		
Applicant WILLIAMS, GEORGE ROGER		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>16</u> sheets.</p>		
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>		
Date of submission of the demand 06 April 2001 (06.04.2001)	Date of completion of this report 10 December 2001 (10.12.2001)	
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer Denise M Pothier  Telephone No. (703) 308-1148	

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/24791

I. Basis of the report

1. With regard to the elements of the international application:*

- ☐ the international application as originally filed.
- ☒ the description:
pages 1-39 as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____
- ☒ the claims:
pages NONE, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages 40-48, 48/1-48/7, filed with the letter of 16 October 2001 (16.10.2001)
- ☒ the drawings:
pages 1-8, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____
- ☐ the sequence listing part of the description:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/~~fig~~ NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US00/24791**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)	Claims <u>1-28</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>1-15 and 20-28</u>	YES
	Claims <u>16-19</u>	NO
Industrial Applicability (IA)	Claims <u>1-28</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 16-19 lack an inventive step under PCT Article 33(3) as being obvious over Lindemann (4,677,971). Lindemann discloses in Figure 9 an orthopedic appliance comprising a palmar component (includes 27), a biasing component (42,53) alignable with the ulnar side of the forearm, the biasing component formed of a continuous wire with a torquing end and supporting end, the torquing end coupled to the palmar component and having a coil (see Fig. 9) formed along its length, and a forearm component (includes 33). However, Lindemann does not disclose the biasing component includes a plurality of adjoining coils formed along its length. One skilled in the art would have known to include a number of adjoining coils along the length in order to provide the desired relative movement between the hand piece and forearm piece as taught in column 4, lines 61-68.

As for claim 17, see the above teaching. The coils are capable of being positioned laterally to the distal forearm/carpal and the carpal/metacarpal joints and slightly dorsal to the axis of the carpus.

As for claim 18, see Figure 9.

As for claim 19, Lindemann discloses in Figure 9 that the palmar component is a splint shell and a means for removably securing (straps) the splint shell to the dorsal side of the forearm. Lindemann also teaches in column 1, lines 57-62 and in column 3, lines 7-13 that limb supports can be made from a deformable, plastic material in order to conform to the shape of the user's hand. However, Lindemann does not disclose the material is semi-rigid. One skilled in the art would know to select a semi-rigid material, since it is desirable to conform the brace to the user for comfort. As such, it would have been obvious to one having ordinary skill in the art to make the forearm component semi-rigid in order to comfortably conform to the user's limb.

Claims 1-28 have industrial applicability as defined by PCT Article 33(4). The claims are directed to an orthopedic appliance and method for treating carpal tunnel syndrome.

Claims 1-15 and 20-28 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest ulnar gutter clasp as recited in claims 1 and 27, the transverse straps as recited in claim 20, the reverse transverse strap as recited in claim 23, and the method steps recited in claim 28.

----- NEW CITATIONS -----

US 5,653,680 A (CRUZ) 05 August 1997, column 4, lines 55-65.

US 4,677,971 A (LINDEMANN) 07 July 1987, see entire document.

US 5,685,013 A (HAUSMAN) 11 November 1997, see col. 4, lines 12-16 and 61-68.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/24791

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61F 5/00

US CL : 602/21; 128/879

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 602/5, 20-22, 64; 128/878, 879

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,657,000 A (HEPBURN) 14 April 1987, see entire document.	1, 4, 5, 14
X	US 5,695,453 A (NEAL) 09 December 1997, see entire document.	1, 4, 5, 7
—		-----
Y		2, 3, 6, 8, 9, 14, 15
A	US 4,862,877 A (BARBER) 05 September 1989, see entire document.	1-20
A	US 5,417,645 A (LEMMEN) 23 May 1995, see entire document.	14, 20

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Z* document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

11 OCTOBER 2000

Date of mailing of the international search report

20 NOVEMBER 2000

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
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What is claimed is:

RECEIVED BY
ART 34 A40T

PTO/PCT Rec'd 04 MAR 2002

1. An orthopedic appliance adapted to be worn on a forearm and a hand of a person exhibiting symptoms of carpal tunnel syndrome, said appliance comprising:

a. a biasing component means having a supporting end and a torquing end, said torquing end disposed to apply a continuous, low level force to the hand over time and in a direction encouraging dorsal glide;

b. a palmar component means coupling said torquing end to the carpal-metacarpal complex of the hand; and

c. a forearm component means rigidly but removably attached to the forearm, said forearm component means providing a stable platform for said supporting end and maintaining alignment of said torquing end with the ulnar side of the carpal-metacarpal complex during movement of the forearm and hand;

whereby contractures of the volar carpal ligaments are relieved and the cocontraction ratio is restored between the flexors and extensors of the forearm, without interfering with normal activities of daily living.

2. The orthopedic appliance described in Claim 1, wherein said palmar component means comprises the following:

- 5 a. an ulnar gutter clasp having a dorsal end and a palmar end, said dorsal end extending from the ulnar side of the hand to approximately the midpoint of the dorsal side of the hand, said palmar end extending from the ulnar side of the
- 10 hand to approximately the midpoint of the palm;
- b. a palmar strap having a fixed end and a attachable end, said fixed end permanently secured to said palmar end of said ulnar gutter clasp, said attachable end passing from said
- 15 palmar end across the thenar web between the thumb and forefinger to said dorsal end and being removably secured to said dorsal end so as to secure said ulnar gutter clasp firmly to the ulnar side of the hand, and
- 20 c. a connection means fixedly attached to said ulnar gutter clasp at a point proximal to the ulnar side of the hand, whereby said torquing end of said biasing component means is coupled to said palmar component means at a point
- 25 outboard of the ulnar side of the hand so as

not to interfere with normal activities of daily living.

3. The orthopedic appliance described in claim 2,
5 wherein said said palmar end is confined within the area of the palm delineated by and interior to the thenar crease of the palm and the MCP joint crease of the palm.

10 4. The orthopedic appliance described in claim 1, wherein said forearm component means comprises the following:

15 a. a body of semirigid material substantially conforming to the dorsum and sides of the forearm, said body having a distal end, a proximal end, an ulnar edge between said distal end and said proximal end, a radial edge between said distal end and said proximal end, and a dorsal portion extending from said distal
20 end to said proximal end and between said radial edge and said ulnar edge; and
b. a distal forearm strap attached to said distal end, encircling the distal forearm, and removably secured by any suitable means.

25

5. The orthopedic appliance described in Claim 4,
wherein said forearm component means further
comprises a proximal forearm strap attached to said
proximal end, encircling the proximal forearm, and
5 removably secured by any suitable means.

6. The orthopedic appliance described in Claim 5,
wherein said forearm component means further
comprises a transverse strap having a first end and
10 a second end, said first end fixedly secured
proximally to said ulnar edge of said body, said
second end passing transversely across the volar
forearm to be removably secured distally to said
radial edge of said body, whereby said transverse
15 strap maintains alignment of the ulnar edge of said
body with the ulna of the forearm during supination
and pronation.

7. The orthopedic appliance described in Claim 5,
20 wherein said proximal end of said body is recessed
to permit unimpeded movement of the extensor muscle
group on the dorsal side of the forearm.

8. The orthopedic appliance described in Claim 6,
25 wherein said body further comprises a radial gap
extending from said radial edge a distance into said

dorsal portion, said radial gap defining a proximal portion and a distal portion, whereby said proximal portion can move relatively independently of said distal portion while both said proximal and distal portions maintain alignment of said ulnar edge with the ulna of the forearm during supination and pronation.

9. The orthopedic appliance described in claim 8, further comprising a transverse tab extending proximally from said distal portion a distance generally along the path of said transverse strap and along said radial edge, said transverse tab providing a fulcrum for said transverse strap during supination and pronation of the forearm.

10. The orthopedic appliance described in claim 4, wherein said forearm component means further comprises the following:

- a. a dorsal gap on said dorsal portion, said dorsal gap extending distally a distance from said proximal end and terminating a distance from said distal end, said dorsal gap defining an ulnar portion and a radial portion extending from said proximal edge, each said portion extending a distance from said proximal end of

said body and unconnected along said distance;
and

b. a dorsal strap spanning said dorsal gap and
extending over the dorsum of the forearm, said
5 dorsal strap having a third end fixedly
connected to said ulnar portion and a fourth
end fixedly connected to said radial portion,
whereby said radial portion and said ulnar portion
move independently within the confines of said
10 dorsal strap.

11. The orthopedic appliance described in claim 10,
wherein said forearm component means further
comprises a transverse strap having a first end and
15 a second end, said first end fixedly secured
proximally to said radial edge of said body, said
second end passing transversely across the volar
forearm to be removably secured distally to said
ulnar edge of said body.

20 12. The orthopedic appliance described in claim 11,
wherein said biasing component means is a continuous
wire from which said supporting end and said
torquing end are composed with a middle segment
25 therebetween, said torquing end positioned along the
ulnar side of the forearm and hand, said torquing

end having at least two adjoining coils fabricated along the length of said torquing end, said adjoining coils positioned laterally to the distal forearm/carpal and the carpal/metacarpal joints and slightly dorsal to the axis of the carpus, said middle segment passing over the dorsum of the forearm, said supporting end positioned along the radial side of the forearm in attachment with said radial portion, said middle segment serving as an axis of rotation for said support end and said torquing end, said transverse strap controlling the dorsal attitude of said torquing end through tension applied to said radial portion and therefore said support end.

15

13. The orthopedic appliance described in claim 12, wherein a first obtuse angle is formed between said middle segment and said support end and a second obtuse angle is formed between said middle segment and said torquing end, whereby said torquing end provides both a force resisting volar glide and simultaneously a slight force promoting ulnar deviation as tension is volarly increased against said support end by said transverse strap.

25

14. The orthopedic appliance described in claim 1,
wherein said biasing component means comprises a
spring having an axis associated with said
supporting end, such that said supporting end of
5 said spring is attached to said forearm component
means and aligned with the ulnar side of the forearm
while said axis is distally positioned on the ulnar
side of the forearm, said torquing end of said
spring attached to said ulnar side of said palmar
10 component means to provide torque opposing volar
movement of said palmar component means at
substantially 20° of dorsiflexion or less, said
support end of said biasing component means
maintaining orientation of and stabilizing said
15 biasing component means along the ulnar aspect of
the forearm during supination and pronation.
15. The orthopedic appliance described in claim 14,
wherein said axis of said spring is approximately
20 positioned on the ulnar side of the distal
forearm/carpal and carpal/metacarpal joints and
slightly dorsal to the axis of the carpus, whereby
an elliptical arc is formed that maintains placement
of said palmar component means throughout extension
25 and flexion of the hand.

16. A method of relieving the pain associated with carpal tunnel syndrome by increasing the carpal volume, while providing minimal impediment to the patient's carpal-metacarpal complex during activities of daily living, said method comprising the steps of
- a. positioning the metacarpal complex of an individual at approximately 20° dorsiflexion, whereby the said 20° dorsiflexion serves as a reference frame for movement;
 - b. providing resistance against volarly directed movement diverging from said reference frame by use of a biasing means approximately positioned on the ulnar side of the distal forearm/carpal and carpal/metacarpal joints and slightly dorsal to the axis of the carpus;
 - c. maintaining alignment of the biasing means during supination and pronation of the forearm; and
 - d. permitting unobstructed flexion of the fingers and opposition of the thumb with the fingers; and
 - e. permitting ulnar deviation of the distal forearm carpal joint.



IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:

— *With international search report.*